

# 510(k) Summary

JUN 1 4 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The a	assigned	510(k)	number:	
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1. Date of submission: March 13, 2013

#### 2. Submitter

SonoScape Company Limited

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## 3. Proposed Device Identification

Trade/Proprietary Name: S11 Digital Color Doppler Ultrasound System

Common Name: Diagnostic Ultrasound System and Transducers

Classification:

21 FR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)

21 FR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

Classification Panel: Radiology

Device Class: II

#### 4. Legally Marketed Predicate Device

SonoScape Company Limited, Diagnostic Ultrasound System, Model S6 has been cleared by FDA through 510(k) No.K112602 (Decision Date – November 07, 2011).

#### 5. Device Description

The SonoScape S11 Digital Color Doppler, Ultrasound System is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The all digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in-depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows cost-effective system integration to a variety of upgrade-able options and features.

This SonoScape system is a general purpose, software controlled, diagnostic ultrasound system. Its basic function is to acquire ultrasound data and display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI, Color-Flow Doppler, Pulsed Doppler and Power Doppler, or a combination of these modes, 4D.

#### 6. Intended Use Statement

The SonoScape S11 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

#### 7. Testing

Laboratory testing was conducted to verify that the S11 system with added transducer met all design specification and was substantially equivalent to the Predicate Device. The device has been found to conform to applicable medical device safety standards in regards to thermal, mechanical and electrical safety as well as biocompatibility. The acoustic output is measured and calculated per "NEMA UID 2: 2004 Acoustic Output

Measurement Standard for Diagnostic Ultrasound Equipment" and "NEMA UD3: 2004 Standards for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment".

IEC 60601-1: 1988+A1:1991+A2:1995 Medical Electrical Equipment - Part 1: General Requirements for Safety

IEC 60601-1-2: 2007 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests. IEC 60601-2-37: 2008 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and

NEMA UD 2-2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Version 3.

NEMA UD3: 2004 Standards for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

#### 8. Clinical Test:

No clinical testing was required.

## 9. Comparison Table

monitoring equipment.

The differences between the S11 and the predicate device S6 in almost every part are listed in the tables below.

**Table 1 General Comparison** 

ID	Comparison Items	Proposed Device Sonoscape S11	Predicate Device Sonoscape S6	Remark
2	Classification Name	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Diagnostic Ultrasound Transducer	SE
3	Product Code	90-IYN/90-IYO/90-ITX	90-IYN/90-IYO/90-ITX	SE

	Comparison			l
ID	Items	Sonoscape S11	Sonoscape S6	Remark
4	Regulation Number	892.1550/892.1560/892.1570	892.1550/892.1560/892.1570	SE
5	Panel	Radiology	Radiology	SE
6	Class	II	11	SE
1	Intended Use	The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), Urology and OB/Gyn.	The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.	SE
7	Probe Type & Connectors	L741 Linear Array, 5.0-10.0 MHz L742 Linear Array, 5.0-12.0 MHz L743 Linear Array, 5.0-10.0 MHz C344 Curved Array, 2.0-5.0 MHz C362 Curved Array, 2.0-6.0 MHz C354 Curved Array, 2.0-5.0 MHz C354 Curved Array, 2.0-5.0 MHz C611 Micro-curved Array, 4.0-8.0 MHz	L741 Linear Array, 5.0-10.0 MHz L742 Linear Array, 5.0-12.0 MHz L743 Linear Array, 5.0-10.0 MHz C344 Curved Array, 2.0-5.0 MHz C362 Curved Array, 2.0-6.0 MHz	SE Analysis 1
		4.0-8.0 MHz  VC6-2 Curved Array, 2.0-6.0  MHz  6V1 Micro-curved Array, 4.0-8.0 MHz  6V3 Micro-curved Array, 5.0-9.0 MHz  EC9-5 Micro-curved Array, 5.0-9.0 MHz	4.0-8.0 MHz  VC6-2 Curved Array, 2.0-6.0  MHz  6V1 Micro-curved Array, 4.0-8.0 MHz  6V3 Micro-curved Array, 5.0-9.0 MHz  EC9-5 Micro-curved Array, 5.0-9.0 MHz	SE
		2P1 Phased Array, 2.0-4.0 MHz	2P1 Phased Array, 2.0-4.0 MHz	SE

510(k) Summary

ID	Comparison	Proposed Device	Predicate Device	Remark
שו	Items	Sonoscape S11	Sonoscape S6	Remark
		5P1 Phased Array, 4.0-7.0 MHz	5P1 Phased Array, 4.0-7.0 MHz	
		Multi-port connector connects 3 transducers	Multi-port connector connects 2 transducers	SE Analysis 2
8	Acoustic Track	TRACK 3	TRACK 3	SE

**Table 2 Functions Comparison** 

ID	Comparison	Proposed Device	Predicate Device	Remark
ן טו	Items	SonoScape S11	SonoScape S6	Remark
		Based on an embedded Linux	Based on an embedded Linux	SE ·
		operating system.	operating system.	
		Based on a 64 channel full	Based on a 64 channel full	SE
		digital beam former.	digital beam former.	
		Autocorrelation for color	Autocorrelation for color	SE
		processing and FFT for pulse	processing and FFT for pulse	
		and CW Doppler processing.	and CW Doppler processing.	
9	Design	Supporting Linear, Curve linear	Supporting Linear, Curve linear	SE
•	Design	and Phase array probes from 2	and Phase array probes from 2	
		to 15 MHz.	to 15 MHz.	
		Cine play back capability	Cine play back capability	SE
		Image file archive	Image file archive	SE
		Software upgrades with USB	Software upgrades with USB	SE
		flash drive.	flash drive.	
		Digital Scan Converter	Digital Scan Converter	SE
j		800×600	800×600	
		TGC 8 slider	TGC 8 slider	SE
	·	Depth Range: 3 to 32 cm	Depth Range: 3 to 32 cm	SE
		Image sector size: 32 lines to	Image sector size: 32 lines to	SE
		full B (256 lines)	full B (256 lines)	
		Image Sector position: Steering	Image Sector position: Steering	SE
		within full maximum	within full maximum	
	Operation	B orientation flip :L/R key with	B orientation flip :L/R key with	SE
10	Controls	marking on the screen	marking on the screen	
i	00	B Dynamic range control:	B Dynamic range control:	SE
		preset 14 curves over 140 dB	preset 14 curves over 140 dB	
		Gray Scale Control: 7 Settings	Gray Scale Control: 7 Settings	SE
		Focal Number: 12 focal zone	Focal Number: 12 focal zone	SE
		setting	setting	
		B persistence: 0-95%	B persistence: 0-95%	SE
		Image Processing: Smoothing,	Image Processing: Smoothing,	SE

ın	Comparison	Proposed Device	Predicate Device		
ID	Items	SonoScape S11	SonoScape S6	Remark	
		edge enhancement	edge enhancement		
		PW sweeping speed 2,4,6,8	PW sweeping speed 2,4,6,8	SE	
		sec over display	sec over display		
		PW Wall filter setting:16	PW Wall filter setting:16	SE	
		settings,25 to 750 HZ	settings,25 to 750 HZ		
		PW sample volume:0.5 to	PW sample volume:0.5 to	SE	
		20mm	20mm		
		PW/B update: with UPDATE	PW/B update: with UPDATE	SE	
		key	key		
		PW cursor steering: Steer soft	PW cursor steering: Steer soft	SE	
		key	key	"	
		PW angle correction:0 to 80	PW angle correction:0 to 80	SE	
		degree user control	degree user control	J_	
		PW spectrum dynamic	PW spectrum dynamic	SE	
		range:10 preset curve over	range:10 preset curve over		
		15-48 dB	15-48 dB		
		Spectrum baseline shift and	Spectrum baseline shift and	SE	
		invert	invert	-	
		Color ROI setting: trackball and	Color ROI setting: trackball and	SE	
		set key to control size and	set key to control size and		
		position	position		
		Color steering on flat probe:±20	Color steering on flat probe:±20	SE	
		±160	±160	0	
		Color Wall Filter: Color wall	Color Wall Filter: Color wall	SE	
		filter with 16 selection, 25-750	filter with 16 selection, 25-750	0_	
		of PRF	of PRF		
		Color priority-B priority soft	Color priority-B priority soft	SE	
		menu	menu		
		Color Packet size: preset per	Color Packet size: preset per	SE	
		Exam, horizontal, vertical, off	Exam, horizontal, vertical, off		
	;	Zoom adjustable	Zoom adjustable	SE	
		Freeze control: Toggling freeze	Freeze control: Toggling freeze	SE	
		key	key		
		Cine control: step, play	Cine control: step, play	SE.	
		backward, play continuously	backward, play continuously		
		B, M, PW, CW, CFM, DPI, TDI,	B, M, PW, CW, CFM, DPI, TDI,	SE	
	Operation	Tissue Harmonic Image	Tissue Harmonic Image	Analysis	
11	Mode	4D Mode	3D/4D Mode	3	
		Color M Mode	Color M Mode	-	
	Display	Dual B, Quad Display,	Dual B, Quad Display,	SE	
12	Modes	B and M, B and Doppler	B and M, B and Doppler	0.	

ID	Comparison	Proposed Device	Predicate Device	Remark
וטו	Items	SonoScape S11	SonoScape S6	Kemark
		B + Color, Dual B(Flow)	B + Color, Dual B(Flow)	
		Triplex mode: B,CFM, and	Triplex mode: B,CFM, and	
		PW/CW ; B,DPI, and	PW/CW ; B,DPI, and	}
		PW/CW;B,THI and Color M,	PW/CW;B,THI and Color M,	
		steer M	steer M	
		Dual B and Color in real time	Dual B and Color in real time	
		Compound Imaging,	Compound Imaging,	
		Panoramic Imaging,	Panoramic Imaging,	
		Trapezoid Imaging	Trapezoid Imaging.	
		Distance; area; circumference;	Distance; area; circumference;	SE
	Measureme nt Items	calipers; volume, velocity, HR,	calipers; volume, velocity, HR,	
13		PI, RI. Cardiac. OB/GYN,	PI, RI. Cardiac. OB/GYN,	
	in items	Urology, Vascular and small	Urology, Vascular and small	
		part package	part package	
		Automatic review/ manual	Automatic review/ manual	SE
14	Cine Loop	review	review	
		Review speed can't be adjust	Review speed can be adjust	SE

Table 3 Specifications Comparison

ID	Comparison Items	Proposed Device SonoScape S11	Predicate Device SonoScape S6	Remark
45	Power	Voltage: 100-240 VAC	Voltage: 110-240 VAC	SE Analysis 4
15	Supply	Frequency: 50/60 Hz	Frequency: 50/60 Hz	SE
		Power Consumption: 100-240V AC, 2.7-1.2A	Power Consumption: 110-240V AC, 2.7-1.2A	SE
		Temperature: 10~40°C Temperature: 10~40°C		ŞE
16	Operating Condition	Relative humidity: 30~85%	Relative humidity: 30~85%	SE
10		Air pressure: 700hPa ~1060hPa	Air pressure: 700hPa ~1060hPa	SE
		Temperature: -20~55°C	Temperature: -20~55°C	SE
17	Storage	Relative humidity: 20~90%	Relative humidity: 20~90%	SE
11	Condition	Air pressure: 700hPa ~1060hPa	Air pressure: 700hPa ~1060hPa	SE
18	Screen Size	15 inch Widescreen LCD monitor	15 inch Widescreen LCD monitor	SE
19	Acoustic Output	Track 3:MI,TIS,TIC,TIB Derated ispta: 720Mw/cm² maximum.	Track 3: MI,TIS,TIC,TIB Derated ispta: 720Mw/cm² maximum.	SE

ID	Comparison Items	Proposed Device SonoScape S11	Predicate Device SonoScape S6	Remark
		TIS/TIB/TIC: 6.0 Maximum,	TIS/TIB/TIC: 6.0 Maximum,	
		Mechanical Index: 1.9	Mechanical Index: 1.9	
		Maximum, or Derated Isppa:	Maximum, or Derated Isppa:	
		190W/cm² max	190W/cm <sup>2</sup> max	

**Table 4 Safety Comparison** 

ID	Comparison	Proposed Device	Predicate Device	Remark
וטו	Items	Sonoscape S11	Sonoscape S6	Remark
20	Electrical Safety	-IEC 60601-1	-IEC 60601-1	SE
21	EMC	-IEC 60601-1-2	-IEC 60601-1-2	SE
22	Performance	-IEC 60601-2-37	-IEC 60601-2-37	SE
23	Biocompatibility	-ISO 10993-5,	-ISO 10993-5,	SE
23		-ISO 10993-10	-ISO 10993-10	
	Level of	Moderate level of concern	Moderate level of concern	SE
24	Concern Of	system	system	İ
	Software			

#### SE Analysis 1

Compare to the predicate device, the proposed device is with one more probe C354. But the intended use of C354 is the same to the C344 and C362, no new intended use is added, therefore, the intended use could be considered Substantially Equivalent.

## SE Analysis 2

The proposed device has 3 probe connection ports and the predicate device has 2 probe connection ports, but both of them comply with IEC 60601-1 and IEC 60601-1-2.

## SE Analysis 3

Operation Mode, compare to the predicate device, the proposed device doesn't have 3D function. But both of them comply with AAMI UD2 and IEC 60601-2-37. Therefore, they are considered to be substantially equivalent, so the SE is not affected.

#### SE Analysis 4

The Voltage of the proposed device and the predicate device are 100-240 VAC and 110-240 VAC respectively, but both of them comply with IEC60601-1 and IEC 60601-1-2. Therefore, power supply can be considered Substantially Equivalent in safety and effectiveness.

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## **Discussion of Substantially Equivalent**

The subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device. The differences above between the subject device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

## 10. Substantially Equivalent Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, SonoScape Company Limited concludes that S11 Digital Color Doppler Ultrasound System is substantially equivalent to predicate devices with regard to safety and effectiveness.





Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

June 14, 2013

SonoScape Company Limited % Ms. Toki Wu Regulatory Affairs Manager Yizhe Building, Yuquan Road, Nanshan Shenzhen, Guangdong 518051 CHINA

Re: K130801

Trade/Device Name: S11 Digital Color Doppler Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX

Dated: March 13, 2013 Received: March 22, 2013

Dear Ms. Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act. include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers for use with the S11 Digital Color Doppler Ultrasound System, as described in your premarket notification:

## Transducer Model Number

2P1 Phase Array	C611 Micro-curved Array	L743 Linear Array
5P1 Phase Array	C362 Curved Array	L741 Linear Array
6V1 Micro-curved Array	C344 Curved Array	L742 Linear Array
6V3 Micro-curved Array	C354 Curved Array	
EC9-5 Micro-curved Array	VC6-2 Curved Array	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its tollfree number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely-yours

Janine M. Morris Deputy Director, Division of Radiological Health Office of In Vitro Diagnostics and Radiological Health

for

Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number: K130801

Device Name: S11 Digital Color Doppler Ultrasound System

Indications for Use:

The SonoScape S11 device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Transvaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

Prescription-Use X AND/OR Over-The-Counter-Use (Part 21 CFR 801-Subpart D) (21-GFR-801-Subpart C)	
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	
Concurrence of CDRH, Office of <i>In Vitro</i> Diagnostics and Radiological Health (OIR)	

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(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130801

System: SonoScape S11

Diagnostic Ultrasound Pulsed Echo System

Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical App	lication	Mo	de o	of Opera	ition				
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic	L							
-	Fetal	Z	N	N		N	N	Note 1	Notes 2,4
	Abdominal ·	Ν	N	N		N	N	Note 1	Notes 2,4
	Intra-operative Specify								
	Intra-operative Neuro	<u> </u>							·
Laparo	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	Notes 2
	Small Organ (specify)	N	N.	N		N	N	Note 1	Notes 2,5
	Neonatal Cephalic	N	N	- N	N	N	N	Note 1	Notes 2,3
Fetal	Adult Cephalic	N	N	N	N	N	N	Note 1	Notes 2,3
Imaging&	Trans-rectal	N	N	N.		N	N	Note 1	Notes 2
Other	Trans-vaginal	N	N	N		N	N	Note 1	Notes 2
	Trans-urethral	Ţ						l	
	Trans-esoph (non-Card)	П							
	Musculo-skeletal (Conventional)	N	N	N		N	N	Note 1	Notes 2
	Musculo-skeletal (Superficial)	N	N	N		N	N	Note 1	Notes 2
	Intravascular								
	Other (Ob/GYN)	Ν	N	N	]	N	N	Note 1	Notes 2,4
	Cardiac Adult	Ν	N	N	N	N	N	Note 1	Notes 2,3
	Cardiac Pediatric	N.	"N"	N	_N	N	N	Note 1	Notes 2,3
Cardiac	Intravascular(Cardiac)								
Cardiac	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel	N	N	N		N	N	Note 1	Notes 2
Vessel	Other (specify)	1							1

N = new inc	lication;	P =	previously	cle	ared by	FDA;	E =	ade	ded under	this	ppend
Note 1: Othe	er Combined	d inclu	udes: B/M; E	3/PV	ND; B/TI	H; M/Co	lor M; B	/Co	lor Doppler	;·B/C	Color
Do	ppler/PWD;	B/Po	wer Dopplei	r/PV	VD.						

Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents

Note 3: TDI Note 4: 4D

Note 5: Small Organ: breast, thyroid, testes

	(Division Sign-Off) ion of Radiological Health
Office of In Vitro	Diagnostics and Radiological Health
510(k)	K130801

Transducer: 2P1 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Cli	nical Application	Mode of Operation								
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify	
Ophthalmic	Ophthalmic									
Fetal	Fetal									
lmaging&	Abdominal	Р	Þ	Р		Р	P	Note 1	Notes 2	
Other	Intra-operative Specify								,	
	Intra-operative Neuro									
	Laparoscopic									
	Pediatric									
	Small Organ (specify)	Г								
	Neonatal Cephalic	Р	P	Р	Р	P	Р	Note 1	Notes 2,3	
	Adult Cephalic	Р	P	Р	Р	Р	Р	Note 1	Notes 2,3	
	Trans-rectal							· ·		
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph.(non-Card)							]		
	Musculo-skeletal								İ	
ı	(Conventional)		1							
	Musculo-skeletal									
	(Superficial)									
	Intravascular								<u> </u>	
	Other (Ob/GYN)	<u>L</u>								
Cardiac	Cardiac Adult	Ρ	Р	Р	Р	Р	Р	Note 1	Notes 2,3	
	Cardiac Pediatric	Р	P	Р	Р	Р	Р	Note 1	Notes 2,3	
	Intravascular(Cardiac)									
	Trans-esoph.(Cardiac)									
	Intra-cardiac									
	Other (specify)									
Peripheral	Peripheral vessel	П								
Vessel	Other (specify)		Ţ							

vessei	Other (specify)	1	L				
N = new ind	ication; P = pre	viously cl	eared by	y FDA;	E = a	dded under	this appendia
Note 1: Other	er Combined includes	: B/M; B/P	WD; B/T	HI; M/C	olor M;B/	Color Dopple	r; B/Color
`Doj	opler/PWD; B/Power	Doppler/P	WD				
Note 2: Tissi	ue Harmonic Imaging	. The feat	ure does	not use	contrast a	gents	
Note 3: TDI	Note 4: 4D						
Note 5: Sma	il Organ: breast, thyr	oid, testes					

_	(Di	vision Sign-Off)
	Division (	of Radiological Health
Office (	of In Vitro Dia	gnostics and Radiological Health
	510/V\	K120901

# Diagnostic Ultrasound Indications for Use Form Transducer: 5P1 Phase Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Cli	nical Application						f Operation		
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	м	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal	Fetal								
lmaging&	Abdominal								
Other	Intra-operative Specify								
	Intra-operative Neuro	Π						-	
	Laparoscopic								
	Pediatric	Р	Р	Р		Р	Р	Note 1	Notes 2
	Small Organ (specify)								
	Neonatal Cephalic	Р	Р	Р	Р	Ρ	Р	Note 1	Notes 2,3
	Adult Cephalic								
	Trans-rectal								<u> </u>
	Trans-vaginal			-					
	Trans-urethral		l						
	Trans-esoph(non-Card)								
	Musculo-skeletal	I					1		
	(Conventional)		<u> </u>						<u> </u>
	Musculo-skeletal								
	(Superficial)		<u> </u>						<b></b>
	Intravascular		<u> </u>					ļ	
	Other (Ob/GYN)	<u> </u>	ļ						
Cardiac	Cardiac Adult				<u> </u>		<u> </u>		
	Cardiac Pediatric	₽	Р	Р	Р	Р	P	Note 1	Notes 2,3
	Intravascular(Cardiac)					ļ <u>.</u>			
	_Trans-esoph.(Cardiac)	_					<u> </u>		
	Intra-cardiac								1
	Other (specify)								<u> </u>
Peripheral	Peripheral vessel								<u></u>
Vessel	Other (specify)							l	<u> </u>

N = new indication;	P = previously cleared by FDA;	E = added under this appendi
Note 1: Other Combined	fincludes: B/M; B/PWD; B/THI; M/Color	M ; B/Color Doppler; B/Color
Doppler/PWD;	B/Power Doppler/PWD	
Note 2: Tissue Harmoni	c Imaging. The feature does not use con	trast agents
NI-4- O. TOL Note	A: 40	

Note 5: Small Organ: breast, thyroid, testes

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7-4 Indications for Use

Transducer: 6V1 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Appli		Мо	de of	Operation	on				
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal	Fetal								
lmaging&	Abdominal								
Other	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic					·			
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	Р	Р	Р		Р	Р	Note 1	Notes 2
	Trans-vaginal	Р	Р	Р		Р	Р	Note 1	Notes 2
	Trans-urethral								
	Trans-esoph.(non-Card)								1
	Musculo-skeletal								
	(Conventional)							]	
	Musculo-skeletal								
	(Superficial)		ļ			-			
	Intravascular								
	Other (Ob/GYN)	<u> </u>							
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	"Intravascular(Cardiac)"	1		<u></u>					
	Trans-esoph (Cardiac)		***********						
	Intra-cardiac								
	Other (specify)							-	
Peripheral	Peripheral vessel				l				
Vessel	Other (specify)								

Peripheral	Peripheral vessel						
Vessel	Other (specify)						
N = new ind	lication; P = previo	usly cle	ared by	FDA;	E = ad	ded under th	is appendix
Note 1: Other	er Combined includes: Ba	M; B/PV	VD; B/Ti	H; M/Co	lor M ; B/C	olor Doppler; I	B/Color
Do	ppler/PWD; B/Power Do	ppler/PW	/D				
Note 2: Tiss	ue Harmonic Imaging. Ti	he featur	e does	not use	contrast ag	ents	
Note 3: TDI					_		
Note 5: Sma	all Organ: breast, thyroid,	testes					
		(Di	vision S	ian_Off)			
	· [	اط) Division o		,	lealth		
	Office of In					lealth	
			5				
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Transducer: 6V3 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Appli		IVIO	ue o	f Operati	)II	1 <del></del>	B	Otherst	
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal	Fetal								
lmaging&	Abdominal								
Other	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic		<u> </u>						
	Trans-rectal	Р	Р	Р		Р	Р	Note 1	Notes 2
	Trans-vaginal	P	Ρ	Р		Р	Р	Note 1	Notes 2
	Trans-urethral					,			
	Trans-esoph.(non-Card)								
	Musculo-skeletal								
	(Conventional)				<u></u>				
	Musculo-skeletal			]	1				
	(Superficial)		<u> </u>						
	Intravascular		<u> </u>						
	Other (Ob/GYN)	ŀ							
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)			3					
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)		Ī	L					
Peripheral	Peripheral vessel								
Vessel	Other (specify)								

Note 1: Other Combined includes: B/M; B/PWD; B/THI; M/Color M; B/Color Doppler; B/Color
Doppler/PWD; B/Power Doppler/PWD
Note 2: Tissue Harmonic Imaging. The feature does not use contrast agents
Note 3: TDI Note 4: 4D
Note 5: Small Organ: breast, thyroid, testes
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510(k)K130801

Transducer: EC9-5 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Appli		Мо	de o	Operation	on			,	,
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal	Fetal			-					
Imaging&	Abdominal								
Other	Intra-operative Specify								
	Intra-operative Neuro						•		
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	Р	P	Р		Р	Р	Note 1	Notes 2
	Trans-vaginal	Р	Р	Р		Р	Р	Note 1	Notes 2
	Trans-urethral							·	
	Trans-esoph.(non-Card)				I				
	Musculo-skeletal		T -						
	(Conventional)	l _							
	Musculo-skeletal		}		1			1	
	(Superficial)		<u>L</u>		<u></u>		<u></u>		
	Intravascular	L							
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric				ļ <u>.</u>				
	*Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Other (specify)								

Vessel	Other (spec	ify)							
N = new ir	ndication;	P = previou	usly cl	leared by	FDA;	E = ac	ded under	this appendi	X
Note 1: Ot	her Combine	d includes: B/l	M; B/P	WD; B/T	H1; M/Cd	olor M ; B/0	Color Dopple	r; B/Color	
D	oppler/PWD;	B/Power Dop	pler/P	WD					
Note 2: Tis	sue Harmon	ic Imaging. Th	ne feat	ure does	not use	contrast ag	gents		
Note 3: TD	I Not	e 4: 4D							
Note 5: Sn	nall Organ: bi	reast, thyroid,	testes	,					
	·	•							
			])	Division S	ign-Off)		-		
		D	ivision	of Radio	ological l	Health			
		Office of In V	/itro Di	iagnostic	s and Ra	adiological	Health		
			•						
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Transducer: C611 Micro-curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Appli		Мо	de o	f Operat	on	,			,
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								<u> </u>
Fetal	Fetal .								<u> </u>
Imaging&	Abdominal .	Р	Р	Р		Р	P	Note 1	Notes 2
Other	Intra-operative Specify								<u> </u>
	Intra-operative Neuro								
	Laparoscopic								
•	Pediatric	ŀΡ	Р	Р		Р	Р	Note 1	Notes 2
	Small Organ (specify)								
	Neonatal Cephalic	Р	Р	P	Р	Р	P	Note 1	Notes 2,3
	Adult Cephalic								
	Trans-rectal .								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph (non-Card)								
	Musculo-skeletal								
	(Conventional)				<u> </u>				<u>l</u>
	Musculo-skeletal								
	(Superficial)		1			<u> </u>			
	Intravascular							<u> </u>	
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	Р	Р	P	Р	Р	Р	Note 1	Notes 2,3
DECINA CONTRACTOR	Intravascular(Cardiac)					-			
	Trans-esoph.(Cardiac)					· · · · · · · · · · · · · · · · · · ·			-
	Intra-cardiac	<u> </u>							
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Other (specify)			1					

Peripheral	Peripheral vessel	1		<u>.</u>			
Vessel	Other (specify)						
N = new inc	dication; P = previo	ously clea	red by FDA	, É = a	dded under	this appendi	X
Note 1: Other	er Combined includes: E	/M; B/PW	/D; B/THI; M/	Color M; B	Color Dopple	r; B/Color	
Do	ppler/PWD; B/Power Do	ppler/PW	'D				
Note 2: Tiss	ue Harmonic Imaging. T	he feature	e does not us	se contrast a	agents	•	
Note 3: TDI	Note 4: 4D						
Note 5: Sma	all Organ: breast, thyroid	, testes					
•							
•		(Div	ision Sign-O/	ff)			
			f Radiologica				
	Office of In	Vitro Diag	gnostics and	Radiologica	I Health		
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Transducer: C362 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applie		Мо	de o	f Operation	on				·
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal	Fetal	Р	P	Р		Р	Р	Note 1	Notes 2
Imaging &	Abdominal	Р	Р	Р		Р	Р	Note1	Notes 2
Other	Intra-operative Specify								ļ
	Intra-operative Neuro								<u> </u>
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal			<u> </u>					
	Trans-vaginal								
,	Trans-urethral							_	
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
٠	Musculo-skeletal (Superficial)								
	Intravascular	Ι	<del> </del>		1				
	Other (Ob/GYN)	Р	Р	Р		Р	Р	Note1	Notes 2
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph (Cardiac)	1							
	Intra-cardiac		1 -						
	Other (specify)								
Peripheral +	Peripheral vessel	Ī							
Vessel	Other (specify)	1		1					

Vessel	Other (specify)							
N = new inc	lication; P	= previou	ısiy ci	eared by	FDA;	E = a	dded under th	nis appendi
Note 1: Oth	er Combined in	cludes: B/	M: B/P	WD; B/T	HI; M/Cd	lor M ; B/0	Color Doppler;	B/Color
Do	ppler/PWD; B/F	ower Dop	pler/P	WD				
Note 2: Tiss	ue Harmonic In	naging. Th	ne feati	ure does	not use	contrast a	gents	
Note 3: TDI	Note 4:	4D						
Note 5: Sma	all Organ: breas	st, thyroid,	testes					
							_	
			•	Division S				
				of Radio				
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Transducer: C344 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Appli		Мо	de o	f Operat	ion				
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic					•			
Fetal	Fetal	Р	Р	Р		P	Р	Note 1	Notes 2
lmaging&	Abdominal	Р	Р	Р		Р	Р	Note 1	Notes 2
Other	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric				•				
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal				-				,
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)							]	
	Musculo-skeletal (Superficial)								
	Intravascular				1				
	Other (Ob/GYN)	Р	Р	Р		Р	Р	Note 1	Notes 2
Cardiac	Cardiac Adult	П		1					
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph (Cardiac)								
	Intra-cardiac	Π							
:	Other (specify)								
Peripheral	Peripheral vessel	Т							
Vessel	Other (specify)	1							

Vessel	Other (specify)					<u> </u>	1	
N = new in	dication; P =	previous	ly cle	eared b	y FDA;	E = a	added unde	er this appendi
Note 1: Oth	er Combined incl	ides: B/M	B/P	WD; B/	ΓΗΙ; M/C	olor M ; B	Color Dopp	ler; B/Color
Do	ppler/PWD; B/Po	wer Dopp	er/P\	ΝD				
Note 2: Tiss	sue Harmonic Ima	ging: The	featu	ire does	s not use	contrast a	agents	
Note 3: TDI	Note 4: 4	D						
Note 5: Sma	all Organ: breast,	thyroid, te	stes					
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			Œ	ivision	Sign-Off	)		
		Div			ological			
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Indications for Use 7-10

K130801

Transducer: C354 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Appli		Мо	de of	Operation	on				
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic							l	
Fetal	Fetal	N	N	N		N	Ň	Note 1	Notes 2
Imaging&	Abdominal	Ν	N	N		N	N	Note 1	Notes 2
Other	Intra-operative Specify						•		
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal								
	(Conventional)								<u> </u>
	Musculo-skeletal								
	(Superficial)			·	•			<u> </u>	
	Intravascular								<u> </u>
	Other (Ob/GYN)	N	N	N		N	N	Note 1	Notes 2
Cardiac	Cardiac Adult	1	Γ					<u> </u>	
	Cardiac Pediatric								
	*Intravascular(Cardiac)		_						
	Trans-esoph (Cardiac)								
	Intra-cardiac							<u> </u>	
	Other (specify)								
Peripheral	Peripheral vessel								
Vessel	Other (specify)			7	1				

N = new indication;	P = previously cleared b	y FDA;	E = added under this appendi
Note 1: Other Combined	includes: B/M; B/PWD; B/	THI; M/Color	M; B/Color Doppler; B/Color
Doppler/PWD; (	3/Power Doppler/PWD		
Note 2: Tissue Harmonio	Imaging. The feature doe	s not use cor	ntrast agents
Note 3: TDI Note	4: 4D		
Note 5: Small Organ: bre	ast, thyroid, testes		
•			
	(Division	Sign-Off)	
	Division of Rad	iological Hea	ilth
	Office of In Vitro Diagnosti	cs and Radio	ological Health
	510(k) <u>K130</u>	0801	

Transducer: VC6-2 Curved Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Appli		Mo	de o	f Operat	ion				
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CMD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								,
Fetal	Fetal	Ρ	Р	Р		Р	Р	Note 1	Notes 2,4
Imaging &	Abdominal	Р	Р	Р		Р	Р	Note 1	Notes 2.4
Other	Intra-operative Specify						-		
	Intra-operative Neuro								
	Laparoscopic		•						
•	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic	Ī						,	
	Trans-rectal	<u> </u>							
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)		Ī						
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular		1						
	Other (Ob/GYN)	Р	Р	Р		Р	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult			İ				Ī	
•	Cardiac Pediatric								
	Intravascular(Cardiac)	1					TANDES AND ASSESSMENT OF THE PARTY OF THE PA		
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
, .	Other (specify)			1		1			
Peripheral	Peripheral vessel		П						
Vessel	Other (specify)	T	l	<u> </u>					

N = new indication;	P = previously cleared	by FDA;	E = added under this appendix
Note 1: Other Combined	d includes: B/M; B/PWD;	B/THI; M/Color I	M; B/Color Doppler; B/Color
Doppler/PWD;	B/Power Doppler/PWD		
Note 2: Tissue Harmoni	c Imaging. The feature do	oes not use conf	trast agents
Note 3: TDI Note	e 4: 4D		
Note 5: Small Organ: br	east, thyroid, testes		
	(Divisio	on Sign-Off)	
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	Office of In Vitro Diagno:	stics and Radiol	ogical Health
•	540(1) (44	100001	
•	510(k)K1	130801	<del></del>

Transducer: L743 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applic		Mo	de o	f Operation	on				
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)						Other* Combined	Other* Specify	
Ophthalmic	Ophthalmic								
Fetal	Fetal								
lmaging&	Abdominal								
Other	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic						•		
	Pediatric								
	Small Organ (specify)	Ρ	P	Р		Р	Р	Note 1	Notes 2
	Neonatal Cephalic								
	Adult Cephalic								<u> </u>
	Trans-rectal								
	Trans-vaginal								ļ
	Trans-urethral								<u> </u>
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	Р	Р	Р		₽	Р	Note 1	Notes 2
	Musculo-skeletal (Superficial)	Р	Р	Р		Р	Р	Note 1	Notes 2
	Intravascular				1		· · · · · · · · · · · · · · · · · · ·		
	Other (Ob/GYN)								<u> </u>
Cardiac	Cardiac Adult								
	Cardiac Pediatric				1.				
	Intravascular(Cardiac)	1-	_		·				
	Trans-esoph.(Cardiac)	1			1				
	Intra-cardiac								
	Other (specify)	T			1				
Peripheral	Peripheral vessel	Р	٠P	Р		Р	Р	Note 1	Notes 2
Vessel	Other (specify)	t		<u> </u>	1				

			1 1					
Vessel	Other (specify)							
N = new ir	dication; P=	revious	y cle	ared by	FDA;	E = a	dded unde	r this append
Note 1: Oth	ner Combined inclu	des: B/M;	B/PV	VD; B/TI	H; M/Cd	olor M ; B/0	Color Doppl	er; B/Color
D-	oppler/PWD; B/Pov	er Dopple	er/PV	/D				
Note 2: Tis	sue Harmonic Imag	jing. The	featur	e does	not use	contrast a	gents	
Note 3: TD	Note 4: 4D	)						
Note 5: Sm	nall Organ: breast, t	hyroid, te	stes				,	
							•	
							_	
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510(k) K130801

Transducer: L741 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Appli		Мо	de o	f Operat	ion				
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic			•					
Fetal	Fetal								
Imaging&	Abdominal					·			
Other	Intra-operative Specify		-						
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	Р	Р	Р		Р	Φ.	Note 1	Notes 2,5
	Neonatal Cephalic				-				
·.	Adult Cephalic								<u></u>
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	Р	Р	Р		Р	Р	Note 1	Notes 2
	Musculo-skeletal (Superficial)							·	,
	Intravascular								<u> </u>
	Other (Ob/GYN)				] · · ·				
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
- 112 : 27	*Intravascular(Cardiac)	_							
	Trans-esoph.(Cardiac)	<b> </b>	_	[					
	Intra-cardiac	Г		I					
	Other (specify)								
Peripheral	Peripheral vessel	Р	Р	·P		Р	Р	Note 1	Notes 2
Vessel	Other (specify)	T		Ì					

N = new indication;	P = previously cleared by FDA;	E = added under this appendix
Note 1: Other Combined	includes: B/M; B/PWD; B/THI; M/Cold	or M ; B/Color Doppler; B/Color
Doppler/PWD;	B/Power Doppler/PWD	
Note 2: Tissue Harmonio	: Imaging. The feature does not use or	ontrast agents

Note 3: TDI Note 4: 4D

Note 3: TDI Note 4: 4D

Note 5: Small Organ: breast, thyroid, testes

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Office of In Vitro Diagnostics and Radiological Health	h

510(k) <u>K130801</u>

Transducer: L742 Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Appli		Мо	de o	f Operati	on				
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	В	м	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal	Fetal								
lmaging&	Abdominal								
Other	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic				I				
İ	Pediatric								
	Small Organ (specify)	Р	Р	Р		Р	Р	Note 1	Notes 2,5
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	Р	Р	Р		P	Р	Note 1	Notes 2
	Musculo-skeletal (Superficial)	Р	Р	Р		Р	Р	Note 1	Notes 2
	Intravascular						·		
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)		_	-					
	Trans-esoph.(Cardiac)								
	Intra-cardiac			e					
	Other (specify)								
Peripheral	Peripheral vessel	Р	Р	Р		Р	Þ	Note 1	Notes 2
Vessel	Other (specify)	Γ							

N = new indication;	P = previously of	leared by FDA;	E = added under this appendix
Note 1: Other Combined	d includes: B/M; B/	PWD; B/THI; M/Color	M; B/Color Doppler; B/Color
Doppler/PWD;	B/Power Doppler/l	PWD	
Note 2: Tissue Harmoni	c Imaging. The fea	ture does not use cor	ntrast agents
Note 3: TDI Note	e 4: 4D	-	
Note 5: Small Organ: br	east, thyroid, teste	S	
-	•	Sur. F)	
		(Division Sign-Off)	<del></del>
•		n of Radiological Hea	ith
	Office of In Vitro	Diagnostics and Radio	ological Health
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